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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/582,946

03/02/2007

Lars-Goran Axelsson

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DLA PIPER US LLP  
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SAN DIEGO, CA 92121-2133

EXAMINER

PITRAK, JENNIFER S

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

04/23/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/582,946	<b>Applicant(s)</b> AXELSSON ET AL.	
	<b>Examiner</b> JENNIFER PITRAK	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-24 and 26-31 is/are pending in the application.
- 4a) Of the above claim(s) 7,8 and 28-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 9-24, 26, and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Remarks***

Applicants amended claims 1, 4, 5, and 13-16; applicants cancelled claims 2, 6, and 25. Claims 1, 3-6, 9-24, 26, and 27 are pending. These amendments obviated the objection of claim 25, obviated the rejection of claims 4, 5, and 13-16 under 35 U.S.C. §112, second paragraph, and also obviated the rejection of claims under 35 U.S.C. §102(e).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any objections or rejections set forth in this Office Action are those that are outstanding. Any previously presented objections or rejections that are not reiterated herein are withdrawn.

### ***Claim Rejections - 35 USC § 103 - maintained***

Claims 1, 3, 4, 9-14, 21-24, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khvorova, *et al.* (2007, US 2007/0031844, filed 11/14/03). Additionally, claims 1-6 and 9-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khvorova, *et al.*, as applied to claims 1, 3, 4, 9-14, 21-24, 26, and 27, further in view of Fosnaugh, *et al.* (US 2003/0143732, filed 08/20/02). These rejections are maintained for the reasons of record presented in the Office Action mailed 11/13/2007, namely that Khvorova teaches SEQ ID NO: 430561, which has a single mismatch with the instantly claimed SEQ ID NO: 9, and suggests that siRNAs with less than 100% complementarity are functional siRNAs and further that the Fosnaugh reference teaches and suggests the claimed siRNA modifications.

Applicants argue that the instantly claimed SEQ ID NOs: 5 and 9 are not obvious because identifying the exact target regions within the 1760 base pair sequence of the NF-kappa-B transcription factor p65 DNA binding subunit that would yield optimal RNA interference presents an undue burden for the skilled person and that the optimal target sequences disclosed in the Khvorova reference are very different than those of the instant application. This is not persuasive because Khvorova specifically discloses siRNAs targeting SEQ ID NO: 430561, which is the exact target region of the instantly claimed siRNAs. Furthermore, the claims do not require that the siRNAs are optimal siRNAs for RNA interference. Thus, the presented arguments are not persuasive and the rejection of the claims is maintained.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK whose telephone number is (571)270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Pitrak, PhD  
Examiner  
Art Unit 1635

/Tracy Vivlemore/  
Primary Examiner, Art Unit 1635